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Dated 24 March 2004

Patents Form 1/77

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The **Patent Office**

1/77

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Request for grant of a patent

(See the notes on the back of this form. You can also get an explanatory leaflet, from the Patent Office to help you fill in this form)

The Patent Office

Cardiff Road
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1.	Your reference	JMCV0331.GB
2.	Patent application number *(The Patent Office will fill in this part)*	0308311.0

11APR03 E799437-3 002806
P01/7700 0.00-0308311.0

3.	Full name, address and postcode of the or of each applicant *(underline all surnames)*	Bristol-Myers Squibb Company 345 Park Avenue New York NY 10154 USA
	Patents ADP number *(if you know it)*	7379902 001
	If the applicant is a corporate body, give the country/state of its incorporation	New York, USA
4.	Title of the invention	Wound Dressing
5.	Name of your agent *(if you have one)*	Barker Brettell
	"Address for service" in the United Kingdom to which all correspondence should be sent *(including the postcode)*	10-12 Priests Bridge LONDON SW15 5JE
	Patents ADP number *(if you know it)*	7442494003

6.	If you are declaring priority from one or more earlier patent applications, give the country and the date of filing of the or of each of these earlier applications and *(if you know it)* the or each application number	Country	Priority application number *(if you know it)*	Date of Filing *(day/month/year)*

7.	If this application is divided or otherwise derived from an earlier UK application, give the number and the filing date of the earlier application	Number of earlier application	Date of filing *(day/month/year)*

8.	Is a statement of inventorship and of right to grant of a patent required in support of this request *(Answer 'Yes' if:* *a) any applicant named in part 3 is not an inventor, or* *b) there is an inventor who is not named as an applicant, or* *c) any named applicant is a corporate body.* *See note (d))*	Yes

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9. Enter the number of sheets for any of the following items you are filing with this form. Do not count copies of the same document

Continuation sheets of this form	
Description	7
Claim(s)	2
Abstract	
Drawing(s)	2 + 2

10. If you are also filing any of the following, state how many against each item.

Priority documents	
Translations of priority documents	
Statement of inventorship and right to grant of a patent *(Patents Form 7/77)*	
Request for preliminary examination *(Patents Form 9/77)*	1
Request for substantive examination *(Patents Form 10/77)*	
Any other documents *(please specify)*	Form FS1 and cheque for £250 (£130 of fees for this application)

11. I/We request the grant of a patent on the basis of this application.

Signature Julie Mays — Date

Barker Brettell — 10 April 2003

12. Name and daytime telephone number of person to contact in the United Kingdom

Julie Mays — Tel: 020 8392 2234

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WOUND DRESSING

The present invention relates to a wound dressing particularly, but not exclusively, for use as a dressing on post-operative wounds that require a drain to remove wound fluid.

For wounds producing some exudate, post-operative wound dressings may be of the type which comprise a thin polymeric film and a low adherency absorbent pad. Such a dressing is sold under the name OpSite Post-Op™ by Smith and Nephew. A disadvantage of such dressings is that if the wound requires drainage via a drainage tube the dressing has to be cut by nursing staff so that the drainage tube can be accommodated.

The absorbent pad also reduces greatly the flexibility of the dressing meaning that a post-operative dressing with an absorbent pad may be difficult to apply to certain areas of the body and particularly around a drainage site and may be uncomfortable to wear. Cutting the dressing to accommodate the drainage tube can release loose fibres from the absorbent pad, which could be lost into the wound, and is a time consuming inconvenience for health care staff.

A further disadvantage is that if it is necessary to cut the dressing, it is not possible to make a complete seal around the incision made for the drain and therefore there is a higher risk of infection. There may also be a higher risk of leakage because the dressings are generally cut to remove a long narrow oblong of dressing, wider than the drain tube, which leaves a corresponding area of the site uncovered. Any wound fluid entering this area will not be absorbed.

There is thus a need for a wound dressing suitable for use on post-operative wounds which is capable of absorbing wound fluid at the rate generally produced by such wounds but which accommodates a drainage tube without the need to cut the dressing.

We have now invented a wound dressing for post-operative sites which alleviates the above problems by combining absorption and the capability to accommodate a drainage tube, the dressing being in a conformable format and there is provided by a first embodiment of the present invention a wound dressing for post-operative sites requiring drainage comprising:

a thin film layer with an adhesive applied to one surface thereof,

an absorbent layer positioned on the adhesive surface of the thin film layer,

the dressing being provided with an aperture to accommodate a drainage tube and

the dressing being slit from the aperture to an outer edge of the dressing.

We have found that wound dressings according to the invention may mitigate the problems associated with applying a dressing to a post-operative site that has a drainage tube. It is thought that this is in part achieved by the aperture and slit in the dressing which aids application of the dressing to the patient by it being possible to position the aperture around the drainage tube and then out and around the drain until the whole dressing is in place.

The thin film layer provides a viral and bacterial barrier to the wound. It is preferably made from polyurethane, has a thickness of 0.02mm to 0.04mm and is transparent. Preferably the thin film layer has a high MVTR. This allows moisture to evaporate from the dressing. The film layer preferably has an MVTR of at least 1500gsm/24hrs as measured by

the method described in BP 1993 Appendix XX J1 or in the range of from 1000gsm/24hrs to 10000gsm/24hrs, preferably 1500gsm/24hrs to 5000gsm/24hrs.

An absorbent layer is preferably present to absorb exudate from the wound. The layer preferably has an absorbency of at least 10 g of sodium chloride and calcium chloride solution (BP 1995 Appendix 1A) per gram of absorbent layer as measured by the absorbency test for alginate dressings BP 1995. The absorbent layer preferably forms the wound contact layer of the dressing and forms a transparent gel on contact with exudate which gel comes into intimate contact with the wound and helps to increase conformability and mobility at the wound site. The absorbent layer is preferably fibrous and most preferably comprises gel forming fibres.

The gel forming fibres are preferably chemically modified cellulosic fibres in the form of a fabric and in particular carboxymethylated cellulose fabrics as described in WO/00/01425 to Akzo Nobel UK Ltd or WO 94/16746 to Courtaulds PLC. The carboxymethylated cellulosic fabrics preferably have a degree of substitution of between 0.12 to 0.45 as measured by IR spectroscopy (as defined in WO/00/01425) and are made by carboxymethylating a woven or non-woven cellulosic fabric such that the absorbency is increased. Particularly preferred fabrics have an absorbency of between 15g/g of sodium/calcium chloride as defined above to 30g/g of sodium/calcium chloride as measured by the method defined above. Particularly preferred fabrics have an absorbency of 20g/g to 30g/g and most preferred of 25g/g to 28g/g of sodium/calcium chloride as measured by the method defined above.

The cellulosic fabric preferably consists solely of cellulosic fibre but may contain a proportion of non-cellulosic textile fibre or of gel-forming

fibre. The cellulosic fibre is of known kind and may comprise continuous filament yarn and/or staple fibre. The carboxymethylation is generally performed by contacting the fabric with strong alkali and a carboxymethylating agent such as chloracetic acid in an aqueous system.

The fabric is preferably of a non-woven type to reduce fibre shedding in the wound.

The absorbent layer preferably has a low lateral wicking rate so that exudate is not spread across the full extent of the layer. This has the advantage of reducing maceration in the skin surrounding the wound. Preferably the lateral wicking rate is from 10mm per minute to 40mm per minute. More preferably the lateral wicking rate is from 10 to 20mm per minute.

The adhesive layer of the present invention is applied to the thin film and may adhere the dressing to the skin for instance where the absorbent layer is an island surrounded by the thin film. Preferably the adhesive composition comprises a homogeneous blend of one or more water soluble hydrocolloids and one or more low molecular weight polyisobutylenes such as are described in EP-B-92999 incorporated herein by reference. The water soluble hydrocolloids may be selected from sodium carboxymethylcellulose, pectin, gelatin, guar gum, locust bean gum, gum karaya and mixtures thereof. The polyisobutylenes may be selected from low molecular weight polyisobutylenes having a viscosity average molecular weight of from 36,000 to 58,000 Florey. The adhesive layer is capable of absorbing exudate while maintaining adhesion of the dressing to the skin.

Alternatively the adhesive composition may comprise a homogeneous blend of one or more hyrdocolloids, one or more low molecular weight

polyisobutylenes one or more styrene block copolymers, mineral oil, butyl rubber, a tackifier and small amounts of optional components. By selection of specific ranges of the amounts of the above listed components, adhesive compositions may be prepared having good adhesion to the skin and stretchability. Such compositions and the preparation thereof are disclosed in EP-B-130061 incorporated herein by reference.

The dressing will typically be made in three sizes, all dressings preferably being about 0.6mm thick. The dressing is preferably circular with a central aperture and curved full-thickness slit which extends from the aperture to the outside of the dressing.

In a second embodiment of the invention, the dressing is preferably elliptical with an aperture positioned towards one end of the long axis of the ellipse and with a curved slit extending from the aperture to an outside edge of the dressing.

Preferably the absorbent pad does not extend to the edges of the slit but is shaped so as to leave a border free of absorbent pad adjacent the slit. More preferably the dressing is provided with additional slits in the form of small cuts extending from the aperture for a short distance into the dressing in the immediate vicinity of the aperture but not extending to the outer edge of the dressing. The cuts are present to accommodate large drain tubes and enhance conformability of the dressing. There are preferably two cuts positioned at 120 degrees to the main slit.

The borders of the slit are preferably free of absorbent pad but are coated with adhesive so that the edges of the slit can be secured to the skin surrounding the wound but also can serve to secure the drainage tube.

Preferred embodiments of the invention will now be illustrated in the following drawings in which:

Figure 1 shows a plan view of a first embodiment of the skin-contacting surface of a wound dressing according to the invention; and

Figure 2 shows a plan view of a second embodiment of the skin-contacting surface of a wound dressing according to the invention.

With reference to the drawings and particularly Figure 1 there is shown a first embodiment of a wound dressing according to the invention. The dressing comprises a central absorbent pad 2, surrounded by an adhesive border 4. The adhesive border 4 is in the form of a thin film which is coated with adhesive and to which the absorbent pad 2 is stuck. This creates a dressing with an island pad 2 surrounded by an adhesive border 4. The dressing is circular in shape to reduce rucking in use and has an aperture 6 at the centre which can accommodate a drain tube (not shown). The dressing has a full thickness slit 8 which extends from the aperture to the outside edge of the dressing. The pad 2 does not extend to the edges of the slit 8 so that adhesive borders are created along the edges of the slit 8. These assist in securing the drain tube.

The slit 8 is further provided with small cuts 10 in the immediate vicinity of the aperture 6 which allow the aperture to accommodate larger sized drainage tubes and enhance the conformability of the dressing.

The slit 8 is curved to aid the sealing of the dressing around the drain tube and reduce the risk of rucking. The curved slit also enhances conformability.

The dressing is applied by positioning the aperture around the drainage tube and then out and around the drain until the whole dressing is in place.

A second embodiment of the dressing is shown in Figure 2. The dressing is of similar construction to that shown in Figure 1 except that the dressing is elliptical in shape. The dressing has an absorbent pad 20 surrounded by an adhesive border 22. The dressing is provided with an aperture 24 and a full thickness slit 26 extending from the aperture to an outside edge of the dressing. The aperture is off-set towards one end of the long axis of the ellipse to allow the dressing to be applied closer to a primary surgical incision site than a dressing with a centrally located aperture could be. The elliptical shape of the dressing allows surgical drain sites to be dressed that are in close proximity to a primiary surgical incision which is also dressed without the dressings overlapping in the area of skin between the two sites.

The wound dressing of the present invention may be made by obtaining an absorbent layer as described in WO 00/01425 and generally in Example 2 of that patent application having an absorbency of 25g/g and a lateral wicking rate of 11mm per minute in the form of a hydroentangled apertured fabric, press cut to the desired shape by a suitable die and bonding it to a polyurethane film coated with a hydrocolloid adhesive described above by conventional heat lamination/pressure techniques. Dressings can be press cut or roller cut from the laminated web.

Claims

1. A wound dressing for post-operative sites requiring drainage comprising:
a thin film layer with an adhesive applied to one surface thereof,
an absorbent layer positioned on the adhesive surface of the thin film layer,
the dressing being provided with an aperture to accommodate a drainage tube and
the dressing being slit from the aperture to an outer edge of the dressing.

2. A wound dressing as claimed in claim 1 characterised in that the dressing is circular in shape.

3. A wound dressing as claimed in claim 1 characterised in that the dressing is elliptical in shape.

4. A wound dressing as claimed in any preceding claim characterised in that the slit takes a curved path from the aperture to an outside edge of the dressing.

5. A wound dressing as claimed in any preceding claim characterised in that the aperture is provided with radial cuts extending from the aperture into the dressing but not to an outside edge of the dressing so that the aperture can accommodate large diameter drainage tubes.

6. A wound dressing as claimed in claim 1 or claim 2 characterised in that the absorbent layer becomes transparent on absorption of exudate.

7. A wound dressing as claimed in any preceding claim characterised in that the absorbent layer is the wound contacting surface of the dressing.

8. A wound dressing as claimed in any preceding claim characterised in that the absorbent layer is fibrous.

9. A wound dressing as claimed in any preceding claim characterised in that the absorbent layer is a carboxymethylated fabric.

10. A wound dressing as claimed in any preceding claim characterised in that the absorbent layer is a carboxymethylated cellulose fabric with a degree of substitution of cellulose groups measured by IR spectroscopy in the range of from 0.12 to 0.45.

11. A wound dressing as claimed in any preceding claim characterised in that it is made from Lyocell and has an absorbency of at least 10g/g of sodium/calcium chloride solution (as defined)

12. A wound dressing as claimed in any preceding claim characterised in that the thin film layer is a polyurethane film.

13. A wound dressing as claimed in any preceding claim characterised in that the film layer extends beyond the absorbent layer to secure the dressing to the skin.

14. A wound dressing as claimed in claim 1 characterised in that an apertured adhesive layer overlies the absorbent layer.

15. A wound dressing as claimed in any preceding claim characterised in that the thin film layer is transparent.

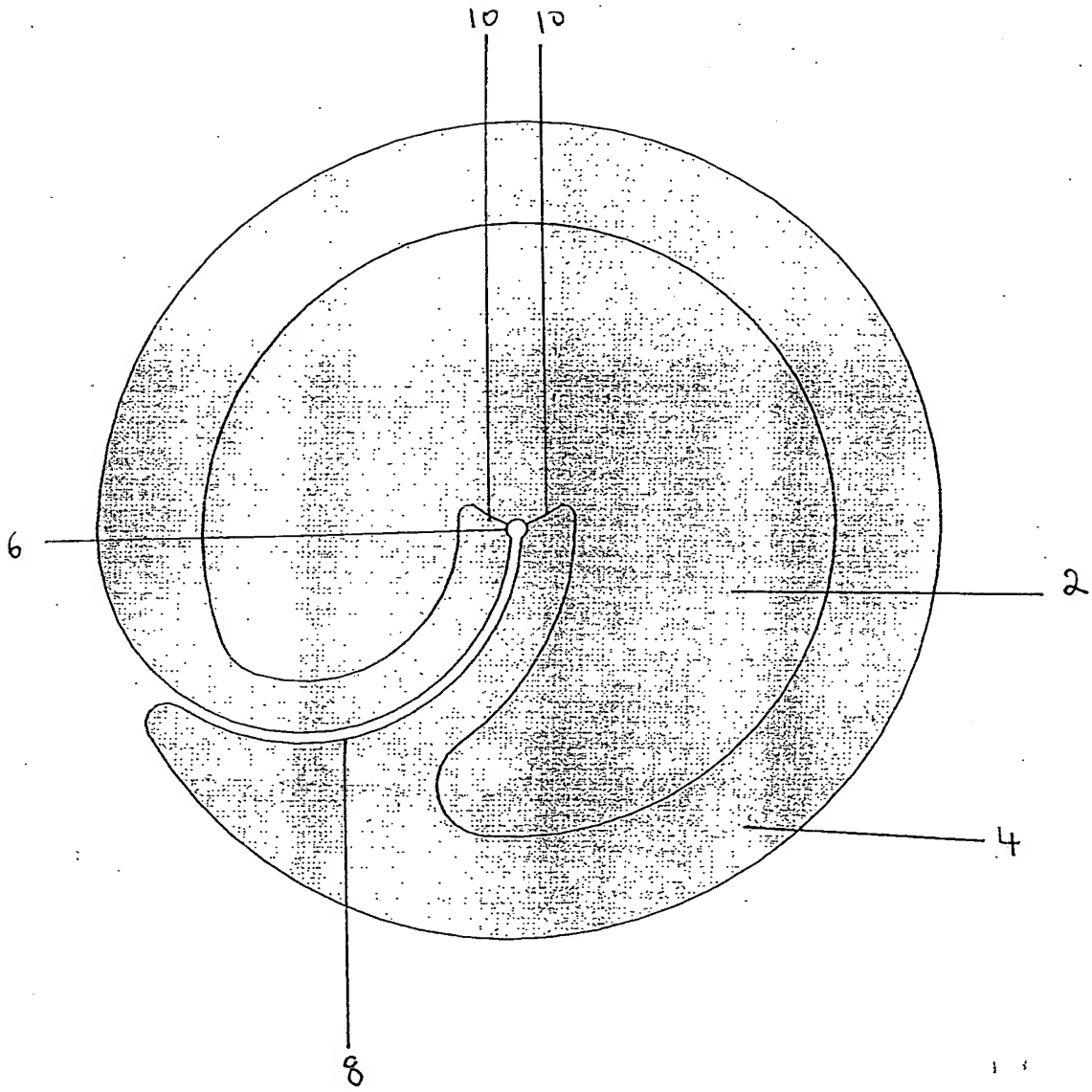

Figure 1

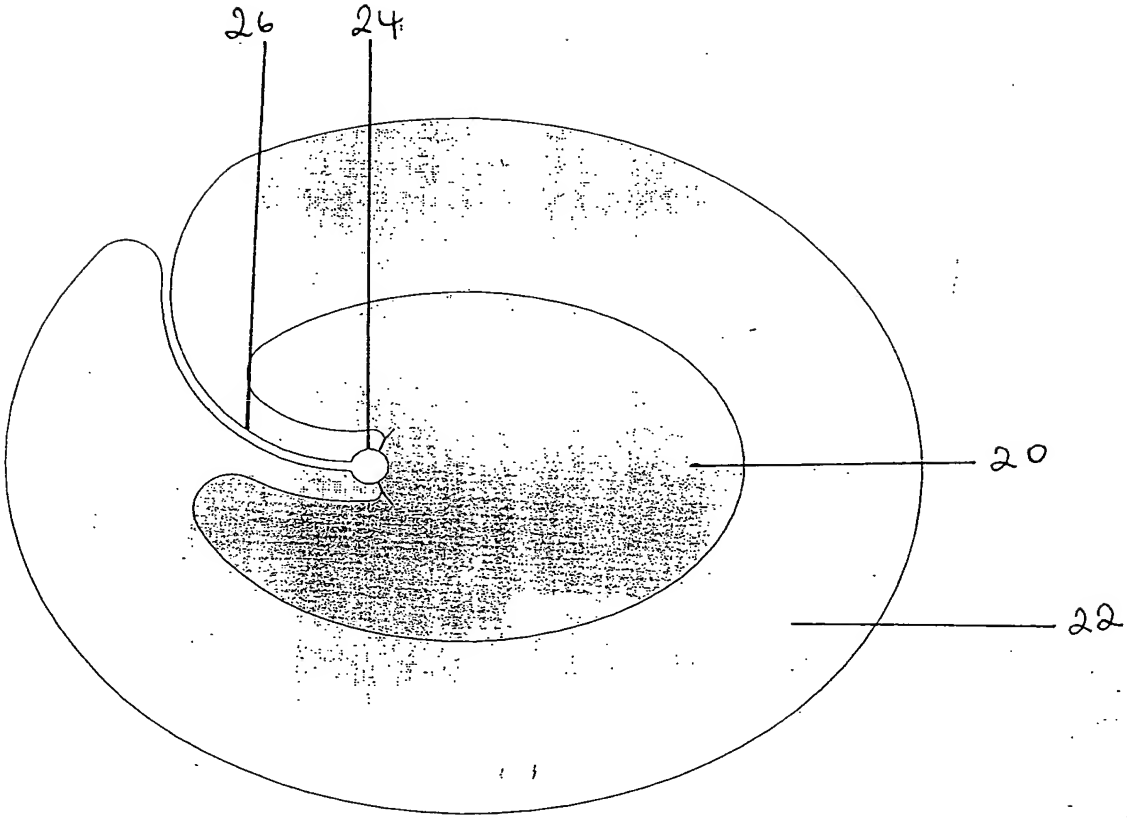

Figure 2